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September 12, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS – 1392 – P
Comments on CMS Proposed Rule on Hospital Outpatient Prospective Payment System for 2008

HOPPS: Payment for Diagnostic Radiopharmaceuticals (RPs) and Nuclear Medicine APCs

Dear Mr. Weems:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to comment on the radiopharmaceutical (RP) and nuclear medicine sections of the proposed rule on the Medicare hospital outpatient prospective payment system (HOPPS) for 2008. 72 Fed. Reg. 42,628 (August 2, 2007). BMSMI is one of the largest manufacturers of RPs in the United States and its products include radiopharmaceuticals for cardiac, neurologic, pulmonary, and other diagnostic imaging procedures important for Medicare patients.

The Centers for Medicare and Medicaid Services (CMS) has proposed very significant 2008 changes in payment for diagnostic RPs that could have an adverse impact on the quality of care for Medicare patients. CMS's proposed changes may over-pay for some products, under-pay other RPs, and could create improper financial incentives for hospitals and physicians to reprioritize patients' clinical needs, select the cheapest priced RP, which could result in lower quality care. Below, we provide a summary of our comments and recommendations, followed by a more detailed analysis.

A. Summary

1. CMS should consider continuing to pay for diagnostic radiopharmaceuticals (RPs) separately from the nuclear medicine procedures.

2. For 2008, payment for diagnostic RPs should be based on CMS's paid claims data with edits/trims that remove inaccurate data for RPs. Such payment should be based on mean calculated cost, consistent with CMS standard methods using CMS's paid claims data from hospitals. CMS could adjust that payment with an add-on for overhead and pharmacy handling costs, to achieve payment that accurately reflects the average acquisition cost.

3. Separate payment for diagnostic RPs will ensure that physicians select the radiopharmaceutical that best meets the patients' medical needs and will support high quality care and access by Medicare beneficiaries.

4. Separate payment will also ensure that Medicare payments in the hospital outpatient setting for Cardiolite®, (Kit for the Preparation of Technetium Tc99m Sestamibi for Injection) and other diagnostic RPs and nuclear medicine procedures are consistent with statutory standards and preserve resource and clinical homogeneity in the APCs.

5. Moreover, in 2008, CMS should consider paying for the highest priced therapeutic radiopharmaceuticals using estimated average acquisition cost (EAAC), as reported by the manufacturer of the specific radiopharmaceutical. In 2009, CMS should consider extending an EAAC method to all therapeutic and diagnostic radiopharmaceuticals.

6. New radiopharmaceuticals should also qualify as new drugs eligible for pass-through payment. Pass-through payment for these new radiopharmaceuticals should be based on established Medicare payment standards, (e.g., Average Wholesale Price) and following completion of the pass-through payment, CMS could use mean calculated cost, edited hospital claims data, EAAC, and consider external cost data, including survey data, to correct for any potential charge compression.

7. CMS should edit hospital reported claims data to ensure that any claims used for nuclear medicine procedure APC or radiopharmaceutical APC rate setting are accurate.

B. Detailed Analysis

1. Problems with CMS's Proposal to Package Diagnostic Radiopharmaceuticals

BMSMI believes there are significant policy, data, and legal challenges with CMS's proposal to package payment for diagnostic radiopharmaceuticals into the payment for nuclear medicine procedure APCs. First, there are radiopharmaceuticals with different clinical and cost features that CMS intends to pay under the same APC. This will overpay some products and underpay others. Packaging radiopharmaceuticals creates serious financial barriers for hospitals and physicians that could block the selection of radiopharmaceuticals based on the patients' clinical needs.

For example, BMSMI makes Cardiolite® (A9500 technetium Tc99m sestamibi), which is one of three different radiopharmaceuticals proposed to be bundled into APCs 398 and 377 (Level I Cardiac Imaging at $346 and Level II/III Cardiac Imaging – at $765.25).

-- Varying product prices can lead to a lack of homogeneity

As noted in the chart below, there are three quite different radiopharmaceuticals with varying prices that CMS proposes to bundle into two APCs. Please note that these three RPs are different chemical entities and there are significant differences in the FDA-approved clinical indications for these RPs.

HCPCS	Descriptor	2006 Mean Unit Cost[1]
A9500	Technetium sestamibi	$84.97/dose
A9503	Technetium tetrofosmin	$74.20/dose
A9505	Thallium	$25.76/mCi or approx. $100 per patient test assuming 3.8 mCi dose

Physicians and/or hospital outpatient departments may select combinations of myocardial perfusion radiopharmaceuticals that could vary in cost from $75 to $170, per myocardial imaging procedure. Paying separately for the radiopharmaceutical preserves the resource and clinical homogeneity in the procedure APCs.

BMSMI also manufactures Neurolite®, (A9557 technetium Tc99m bicisate) with 2006 unit cost of $270. CMS proposes to bundle this radiopharmaceutical into APCs 403 and 402, with proposed payment levels of $212 and $563. Clearly, these APC payment levels for the procedures do not adequately account for the cost of the radiopharmaceutical.

2. CMS Packaging of Add-on Procedures Exacerbates Problems

CMS is also proposing to bundle certain cardiac add-on procedures in cardiac imaging: (78478 – heart wall motion, 78480 – heart function add-on, and 78496 – heart first pass add-on) into APC 377. The selection of add-on procedures can trigger widely varying resource costs and may undermine the clinical and resource homogeneity of the nuclear medicine APCs, especially the cardiac imaging APCs.

3. Flaws in Restructured Cardiac Imaging APCs

CMS is also proposing to restructure Level I Cardiac Imaging so that it would contain 14 procedures that differ widely clinically and in terms of resources. This Level I Cardiac Imaging APC would have all radiopharmaceutical costs packaged. Keeping separate payment for radiopharmaceuticals would contribute to an APC that was clinically homogenous and similar with respect to resources, as the statute requires (See Social Security Act, section 1833(t)(2)(B).

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1 See CMS Tables 3 and 4, Radiopharmaceuticals With a Mean Unit Cost Increase/Decrease between 2005 and 2006, presented by CMS to APC Advisory Panel Meeting (March 7, 2007).

4. No Authority to Bundle/Package Radiopharmaceuticals

CMS proposes to bundle/package diagnostic radiopharmaceuticals suggesting that they are "supplies". FDA regulates radiopharmaceuticals as drugs. Equally if not more important, the Medicare HOPPS statute consistently recognizes all radiopharmaceuticals as drugs and specified covered outpatient drugs. See, for example, Social Security Act section 1833(t)(14)(B). Under this authority, CMS has treated radiopharmaceuticals as drugs for reimbursement under HOPPS. CMS does not have the authority to differentiate radiopharmaceuticals from other drugs and bundle diagnostic radiopharmaceuticals into the procedure APC merely based on the characterization that they are supplies. Radiopharmaceuticals, including diagnostic radiopharmaceuticals, qualify as "specified covered outpatient drugs" (SCODs) and should be covered separately and paid consistently with the statutory standard for average acquisition cost, and accounting for the unique overhead/pharmacy handling costs needed to provide radiopharmaceuticals safely.

5. Packaging Violates Two-Times Rule

Packaging of all the various cardiac imaging radiopharmaceuticals and add-on procedures would, in our opinion, violate the "two-times" rule. CMS has moved all the CPT codes previously in Level II and Level III Cardiac Imaging (except CPT 78465) into Level I Cardiac Imaging. CMS has essentially created a new Level II Cardiac Imaging APC, with a proposed payment level of $765.25, containing only one primary procedure (CPT 78465 – Myocardial perfusion imaging; tomographic (SPECT), multiple studies (including attenuation correction when performed), at rest or stress (exercise and/or pharmacologic), with or without quantification). This Level II Cardiac Imaging APC is intended to pay for various combinations of primary and add-on procedures, radiopharmaceuticals, and cardiac stress agents.

Different combinations of add-on procedures can be performed. Packaging all the radiopharmaceuticals (at low and high costs) and add-on procedures into the same APC would trigger widely varying resources that violate the "two-times" rule. A "simple" myocardial SPECT procedure, done with thallium and no add-on procedures, would use significantly lower resources, compared to a "complex" myocardial SPECT procedure with Cardiolite® and multiple add-on procedures. In like fashion, the consolidation of all the remaining cardiac imaging procedures from two into one APC (Level I Cardiac Imaging) "force-fits" many different procedures with widely varying resources into one payment level. Comparing the resources of the different procedures in the proposed consolidated cardiac imaging APCs clearly demonstrates a violation of the "two-times" rule. Further, we do not believe this is a justification or explanation for exempting this APC from the "two-times" standard. Retaining separate payment for radiopharmaceuticals would contribute to more uniform and homogeneous resources in the newly configured APCs.

6. Recent changes not yet in effect – loss of data

CMS has recently implemented (2007 will be the first full year) distinct revenue codes for diagnostic and therapeutic radiopharmaceuticals. Hospitals have not yet fully implemented these revenue codes into billing practices. The payment for radiopharmaceuticals as a packaged unit risks the hospitals abandoning separate charging for these drugs. That, in turn, can lead to loss of key data about radiopharmaceuticals and fundamentally inaccurate data for

purposes of further weighting and payment adjustments. Deficient data could trigger improperly low payment and barriers to appropriate use. Packaging under these circumstances may not only be problematic but perhaps also premature.

7. Improper incentives

Packaging could most likely create unforeseen and unwanted financial incentives so that hospitals could select a specific radiopharmaceutical based on lowest cost rather than selecting the product that produces high quality care and is clinically most appropriate for the patient's particular medical needs.

With separate payment for each diagnostic radiopharmaceutical, physicians and hospitals choose the radiopharmaceutical that makes the most clinical sense. Packaging triggers a heightened sensitivity to product payment differences, which would not be consistent with quality care.

8. Edits to Hospital Claims Data

On September 6, 2007, the APC Advisory Panel recommended that CMS implement special edits to hospital claims data for nuclear medicine procedures and radiopharmaceuticals. BMSMI supports this recommendation. One specific edit would be to put CPT code 83017 on the by-pass list. This would correct methodological and data flaws that are resulting in improper payment for cardiac imaging APCs. Cardiac imaging often requires multiple procedures. Multiple procedure data are being lost and thus values for cardiac imaging are undervalued.

C. Recommendations

1. CMS should continue to pay separately for diagnostic radiopharmaceuticals, including Cardiolite®, and other myocardial perfusion imaging agents.

2. In 2008, payment for Cardiolite® and other myocardial perfusion imaging agents should be based on mean calculated costs from CMS's paid claims data and with any edits or trims in that data to remove inaccurate hospital data. CMS should adjust those payment amounts to include an appropriate amount covering the unique overhead and handling costs for safe preparation, administration and disposal of radioactive isotopes. This will be the most accurate proxy for hospital average acquisition costs, the statutory standard.

3. In 2008, CMS should also begin to accept from the manufacturers of high priced therapeutic radiopharmaceuticals an estimated average acquisition cost (EAAC). Since radiopharmaceutical manufacturers do not have average sales prices (ASP), manufacturers should begin a new process of estimating the acquisition cost, and reporting this amount to CMS as a basis for payment. Looking ahead to 2009, as the methods for estimating EAAC for radiopharmaceuticals are better developed, this method could be expanded for other radiopharmaceuticals, including diagnostic radiopharmaceuticals. We strongly urge CMS that since such estimates do not have the same precision as conventional ASP calculations, that manufacturers only be

held to an appropriate standard (for example: reasonable efforts to accurately estimate) for such EAAC reporting.

4. CMS should apply similar hospital billing standards to radiopharmaceuticals that are required for other drugs. That is, hospitals should be required to separately report the charge for the radiopharmaceutical, and also pharmacy overhead, and handling costs, as part of the RP charge. This will enable CMS to develop accurate data and appropriate payment for handling costs. MedPAC established that radiopharmaceuticals have the highest overhead costs, and CMS data do not yet capture nor pay for radiopharmaceutical overhead and handling costs.

BMSMI strongly encourages CMS to adopt the recommendations made above. In so doing, HOPPS payment will better support high quality care for Medicare beneficiaries. We would welcome the opportunity to discuss these recommendations in greater detail. Should you have any questions, please contact Jack Slosky, Ph.D., FASNC, at jack.slosky@bms.com or (978) 671-8191.

Thank you for your consideration.

Sincerely,

T Ravenscroft

Timothy Ravenscroft
President
Bristol-Myers Squibb Medical Imaging

Cc: Herbert B. Kuhn
Carol Bazell, M.D. (CMS)
American College of Cardiology
American College of Radiology
American Society of Nuclear Cardiology
Council on Radionuclides & Radiopharmaceuticals
Nuclear Medicine APC Task Force
Society of Nuclear Medicine

BKD LLP

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September 12, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS–1392–P
August 2, 2007, OPPS Proposed Rule
Submission of Comments

Dear Sir or Madam:

We appreciate this opportunity to comment on the outpatient PPS (OPPS) fiscal 2008 proposed rule published in the August 2, 2007, **Federal Register**. We are a regional CPA and consulting firm serving approximately 400 hospitals nationwide. Our comments are as follows:

Necessary Provider CAHs

CMS proposes several changes related to critical access hospitals (CAHs). First and foremost, we are concerned that CMS proposes these changes in the OPPS proposed rule. As CAHs are exempt from OPPS, we are troubled that CMS proposes such changes in this proposed rule, which is not read by many CAHs. Such proposed changes should be the subject of a separate proposed rule where more CAHs would be able to evaluate it without having to sift through hundreds of pages of data that is irrelevant to them.

With regard to the specific changes CMS proposes, the proposed regulations appear to be a solution in search of a problem. The prospect of new co-location agreements between a CAH and a psychiatric or rehabilitation hospital seems very slim. Additionally, a psychiatric or rehabilitation hospital gains no Medicare reimbursement advantage by virtue of co-location with a CAH. If two providers combine locations to improve operating efficiencies, this likely reduces costs to the Medicare program in the long run, as the CAH will presumably have lower operating costs reported on its Medicare cost report and therefore lower reimbursement.

We agree that it would be inappropriate for a CAH to be co-located with another CAH or an acute care PPS hospital and would not oppose CMS clarifying that position in regulation.

However, prohibiting co-location with other types of providers is misguided. It occurs very infrequently, does not cause any harm to the Medicare program; and when it does occur, it leads to cost effective high quality delivery of health care services to Medicare beneficiaries and others that need the services.

With regard to provider-based facilities, provider-based psychiatric or rehabilitation units dilute the Medicare costs of the host CAH, whether on campus or off, with no reimbursement benefit to the psychiatric or rehabilitation unit. Therefore, operating such units reduces costs to the Medicare program, and should not require additional regulations to prevent off-campus operations.

We acknowledge that provider-based outpatient clinics, including rural health clinics, are cost-reimbursed to a CAH. However, such clinics tend to have lower Medicare utilization percentages than the hospital's Medicare inpatient utilization percentage. Thus, they also dilute Medicare reimbursement to the hospital itself. A CAH will typically operate such provider-based facilities simply to be able to serve the needs of a rural population in what are frequently isolated locations with few alternative sources of primary health care. Additionally, these outpatient clinics have no licensed beds and offer no inpatient care. For these reasons, we do not believe it is appropriate to subject them to the statutory CAH distance requirements applicable to a new critical access hospital.

Finalizing this proposed regulatory change will do little to reduce costs to the Medicare program but will do much to restrict access to care for rural Medicare beneficiaries. It would only diminish CAHs' ability to provide for efficient cost effective delivery of quality services. For these reasons, we request that CMS eliminate these proposed regulatory changes.

* * *

We appreciate this opportunity to comment on these important proposals. If you have any questions concerning our comments or require further information, please contact Tim Wolters at 417-865-8701.

BKD, LLP

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September 12, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule; CMS-1392-P

Dear Acting Administrator Weems:

.decimal is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 2, 2007 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule as it relates to the 2008 packaging proposal.

OPPS: PACKAGED SERVICES-PROPOSED PACKAGING APPROACH

For 2008, CMS proposes to package payment for items and services in the following seven categories into the payment for the services with which they are furnished: 1) guidance services; 2) image processing services; 3) intraoperative services; 4) imaging supervision and interpretation services; 5) diagnostic radiopharmaceuticals; 6) contrast agents; and 7) observation services.

.decimal supports the APC Advisory Panel's September 6, 2007 recommendation to exclude all image guidance codes (CPT 76950, 76965, 77014, 77417 and 77421) used in conjunction with radiation oncology procedures from the 2008 proposal to package guidance services.

.decimal is very concerned that the proposed reimbursement structure will create an incentive for hospitals to cut back their use of advanced technologies for daily patient localization used in radiation oncology treatment delivery, including IMRT in a way that could have a direct negative impact on the quality of patient care. The goal of radiation therapy is to maximize the radiation dose to the tumor site while minimizing the dose to surrounding healthy tissue. .decimal believes that the use of state-of-the-art radiation oncology treatment delivery modalities without the corresponding use of adequate daily target localization presents a serious safety risk to patients, and the current proposal seems to offer a financial incentive to those hospitals that choose to make little or no use of daily localization when providing radiation therapy.

Further, .decimal is concerned that the methodology to determine payment for packaged services is not transparent and may lead to inappropriate payment for image guidance services associated with intensity modulated radiation therapy (IMRT). CMS should make all relevant data associated with the packaging proposal available to the public in a no-cost format on the CMS website.

.decimal believes that the CMS proposal to package payment for guidance services in 2008 will produce inaccurate APC configurations and decreased rates in future years and will discourage adoption of new technologies and continued innovation. Appropriate payment for radiation oncology procedures, including IMRT is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in the hospital outpatient setting.

We hope that CMS will take these issues under consideration during the development of the 2008 HOPPS Final Rule. Should CMS staff have additional questions, please contact me at (407) 330-3300.

Sincerely,

Richard Sweat

Richard Sweat
President & CEO

Madison Parish Hospital
900 Johnson St. - PO Box 1559
Tallulah, LA 71282-1559

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Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Delivered Via On-Line Form: http//www.cms.hhs.gov/eRulemaking

Subject: CMS-1392-P- Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals.

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above; specifically in regards to proposals made affecting the Critical Access Hospital (CAH) program. I am the administrator at Madison Parish Hospital in Tallulah, Louisiana. Madison Parish Hospital is a publicly owned and operated hospital.

Madison Parish Hospital serves a rural population in the Mississippi River Delta with a poverty rate of approximately 40% and an unemployment rate of 17%. This hospital was granted CAH status on January 1, 2005 and is stipulated a Necessary Provider by the State of Louisiana. The proposed change as listed above will negatively affect the improvement in access to care for years to come in Madison Parish. We serve a population that has an extremely high percentage of people with diseases such as hypertension, diabetes, asthma, chronic obstructive pulmonary disease and cancer.

Madison Parish Hospital has in its plans the opening of at least one rural health clinic more closely located to the population base that we serve, primarily the poor and elderly. Many of the patients we serve have no form of transportation and access to health is very difficult for them. The hospital plans to open the clinic in a closer proximity to the patient base thereby improving access to primary care and reducing cost to the patient and the taxpayer. It would be impossible to have the clinic built and certified by January 1, 2008.

C. W. Alford
Administrator

Phone (318) 574-2374
Fax (318) 574-2396

Madison Parish Hospital
900 Johnson St. - PO Box 1559
Tallulah, LA 71282-1559

I respectively ask that you withdraw the provisions of this rule pertaining to off-site primary care delivery systems owned by CAHs. These provisions would have a devastating impact on the access to health care in our rural community. I believe this is contrary to the intention of the CAH program. Provisions of this nature would eliminate our ability to provide the care needed in rural communities for today and for the future.

Thank you for considering my comments. Please contact me if you have any questions.

Sincerely,

C. Wendell Alford, R.Ph.
Administrator
Madison Parish Hospital
(318) 574-2374

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STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504-7853

September 12, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 1392-P
Post Office Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

This letter addresses proposed regulation regarding Necessary Provider CAHs. The proposed regulation could be damaging to rural health care in Washington. It would eliminate the ability of some Critical Access Hospitals to establish Rural Health Clinics if the clinic were to lie outside the mileage restrictions for the hospital.

Please note the following statistics:
39 Critical Access Hospitals in Washington;
12 Critical Access Hospitals have Rural Health Clinics in other towns;
28 Rural Health Clinics are affiliated with these Critical Access Hospitals; and
38 unduplicated communities with a CAH supported RHC.

Fourteen of these Critical Access Hospitals are located in small rural counties with a combined population of 458,600. To restrict where a Critical Access Hospital might locate a rural health clinic could have a *significant* impact on rural health care in Washington.

Provider-based outpatient clinical services provide a cost-effective complement to hospital services. They greatly reduce reliance on the emergency department for non-emergent care. Clinics also reduce the time frame in which patients may be seen and treated. The existence of a provider-based Rural Health Clinic enhances the ability of Critical Access Hospitals to provide necessary, cost-effective care within the communities they serve. Critical Access Hospitals need to have the freedom to establish such clinics when the need becomes apparent.

We recommend that the proposed regulation include an exemption for the creation or acquisition of provider-based Rural Health Clinics by necessary provider Critical Access Hospitals.

Thank you very much for the opportunity to comment and for your consideration of these concerns.

Sincerely,

Kristina M. Sparks
Office of Community and Rural Health

Chatham
HOSPITAL

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September 10, 2007

Centers of Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P (NECESSARY PROVIDER CAH'S)
P.O. Box 8011
Baltimore, MD 21244-1850

RE: NECESSARY PROVIDER CAH'S

To Whom It May Concern:

This letter is to comment on the notice of proposed rulemaking for Hospital Outpatient Prospective Payment System (OPPS) that includes proposals specific to Critical Access Hospitals (CAH). This proposed rulemaking was published on July 16, 2007 and will be effective January 1, 2008 if implemented.

Chatham Hospital converted to Critical Access Hospital (CAH) status in May 2002 under the necessary provider provision. This conversion allowed our hospital to remain a viable entity after the closing of multiple textile companies. Our inpatients are primarily geriatric and are covered by either Medicare or Medicare Advantage plans. Approximately 25% of the Emergency Room patients are self-pay. About 10% of our patients are Medicaid. The conversion to CAH status has allowed this hospital to stabilize and to continue to operate. With the help of HUD 242 financing, we are in the midst of constructing a new hospital to be opened in the summer of 2008.

I express serious concern about the provisions in the proposed rule which will eliminate the potential of a necessary provider, or any CAH, to establish a provider based location including a department or a remote location or an off campus distinct part psychiatric or rehabilitation unit on or after January 1, 2008 that does not meet the distance criteria for CAH from another hospital or CAH. The penalty for establishing such a unit can be the loss of CAH certification. CMS proposes, "...any off campus location must satisfy the distance requirements, without exception and regardless of whether the main provider CAH is a necessary provider CAH." This proposal has significant potential to create a negative situation for Chatham Hospital. It will impact access to care for Medicare beneficiaries in our rural community.

Chatham County is predominantly rural and covers approximately 700 square miles. It is one of NC's fastest growing counties. In addition, we have a large Hispanic community. We believe that potential access will be diminished in our rural community if we are unable to establish health care services in remote locations. We have found that many of our patients do not have

transportation and that we must be able to bring services closer to their homes. It is our fear that this legislation will prevent us from doing that.

We therefore recommend that you alter this provision and encourage you to stay with the existing provisions that include that 75% of the patient population must be from within the primary service area of the critical access hospital. Thank you for your consideration of this matter.

Sincerely,

Carol Straight

Carol Straight
CEO

UNC HEALTH CARE

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RFGH

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September 12, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P, Main Stop C4-26-05
750 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Sir:

We are writing in opposition to the changes proposed to provider-based units as published in the August 2, 2007 Proposed Rules. We do however have fundamental agreement the position taken in those rules that "the intent of the CAH program is to keep hospital-level services in rural communities, thereby ensuring access to care". A key aspect of ensuring the provision of hospital-level services and ensuring access to care to Medicare beneficiaries living in our rural community is the availability of physicians. Since the proposed rule changes will make the future designation of provider-based units either impossible or at best more difficult, their implementation will make the recruitment/retention of physicians in our rural areas more difficult, and therefore in contradiction to the stated intent.

Redington-Fairview General Hospital is a 25 bed CAH, located approximately 25 miles from the nearest Hospital whose only access to our community is through secondary roads. The Hospital was deemed a "necessary provider" by virtue of the demographics of our service area which has a disproportionate share of elderly and individuals living below the Federal poverty guidelines. Our service area has 16.2% of the population living at 100% of the Federal Poverty Guidelines, 15% of the population over the age of 65 and 7.5% unemployment rate (source: 2000 census). These ratios compare with the State of Maine averages of 10.9% living at 100% poverty level, 14.4% of the population over the age of 65 and an unemployment rate of 5%. Maine ranks 43rd in per capita income and has the third highest percentage of elderly population in the United States. Not surprisingly, prior to our licensing as a CAH, the Hospital was a Medicare Dependent Hospital. Our current payor mix is approximately 75% Medicare/Medicaid. Located in a MUA (a medically underserved area), we also serve a large percentage of disabled individuals who receive Social Security benefits. If the rules are promulgated as proposed, this patient population will be denied access to care and new services.

We are opposed to proposed rule change as written for the following reasons:
1) as stated in our introductory remarks, the implementation will make designation as a provider based unit more difficult and consequently, disrupt the recruitment/retention of physicians, eliminate the future provision of new services and new construction 2) the proposed rule change will make rules

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surrounding the designation of provider-based units inconsistently applied among Hospitals, 3) by making the designation of provider-based units impossible, options for retaining/recruiting physicians will be frozen on January 1, 2008 creating different classes of physicians within rural communities; 4) the proposed rule change would make relocation for one department a CAH different than the entire CAH; 5) in attempting to apply consistency to two different concepts (CAH and Provider-Based Units) the implementation of the proposed rule will deny some rural areas from receiving access to care.

Undermine Physician Recruitment and Retention

Rural providers face unique financial constraints (high Medicare and indigent patient population, for example). These unique financial constraints led Congress to establish and then expand the CAH program in order to attempt to shore up the financial viability of rural hospitals and thereby provide access to Medicare beneficiaries. As physicians found themselves unable to cope with payment shortfalls inherent in rural populations, they have turned to Hospitals for help. At Redington-Fairview General Hospital, the result has been a steady stream of physicians moving from private practice into the Hospital as provider-based units. In Somerset County, this change occurred prior to our licensing as a Critical Access Hospital and has continued after our CAH designation. While retaining physicians and improving care to patients through the clinical integration of the practices was the foremost reasons in considering designation as provider-based units, another important factor was the financial impact. Prior to our licensing as a CAH, the change resulted in a significant increase in payment under PPS which allowed the Hospital to establish systems which would help to retain and recruit physicians. Another important financial consideration was that physicians in the provider-based unit would see patients without regard to their financial ability to pay for the services. The positive financial impact was significantly reduced when the Hospital converted to CAH status. However, while the financial benefit is significantly less with our CAH licensure, we still would not have been able to provide the necessary level of support to these physicians, without this designation. Consequently, we would have been unable to recruit/retain physicians who would treat patients without regard to their ability to pay. In our community, the specific groups that would have suffered were Medicaid recipients and the indigent. So, while cost reimbursement is considerably less financially beneficial as a CAH than under PPS, the proposed rule would undermine what little benefit we are receiving, thereby, hindering our ability to provide a competitive practice opportunity for our physicians while at the same time providing equal access to all the community.

Inconsistent Application of Rules among Hospitals

The rules that CMS promulgates for Hospitals generally either require the same compliance for all Hospitals or are tailored to the Hospitals unique circumstances. For example, regulations recognize that Hospitals who serve a high percentage of indigent or low income population will have a more difficult time financially than an urban hospital with a low percentage of indigent patients (disproportionate share rules). However, the

proposed rules pertaining to the designation of provider-based units will mean that the qualifying criteria will be inconsistently applied amongst hospitals. These rules create an uneven playing field among hospitals, with "necessary providers being the most restricted. Hospitals who are PPS would not be subject to a rule which requires that their provider-based unit be 35 miles from another Hospital, so in effect, a PPS Hospital could open a provider-based unit in a community that a CAH serves. That same CAH, however, would be precluded from receiving that designation if the unit were not 35 miles from another Hospital. We don't believe that this inconsistent application is either good public policy, nor benefits the community and Medicare beneficiaries.

Different Classes of Physicians

Presently, we have some physicians who are remaining in private practice. As we discussed above, they maintain the solvency of their practice by limiting the amount of Medicaid recipients and indigent patients that are allowed into their practice. As we stated earlier, the physicians in provider-based units see all patients regardless of their ability to pay. If these rules are implemented, these differences will be frozen in time. If circumstance change (economic downturn in the local community, a change in the social consciousness of the physicians, etc.), these physicians in private practice will not be allowed to become a provider-based unit in the Hospital. The regulations will have created different classes of physicians in the same rural community.

The Rules for relocation would be different (prohibiting even on campus provider-based units from relocating closer to the Hospital)

The rule as proposed would preclude any new construction of medical office space for physicians practicing in provider-based units whether on-campus or off-campus. Since a provider-based designation is site specific, any relocation to new space would be a material change. Obviously, since a necessary provider does not meet the mileage requirement, therefore, by definition, any new provider-based unit or any provider-based unit which would need to relocate, even closer to the Hospital and the community being served would be required to relinquish its status. Thus, the requirement for one department of the Hospital would be more stringent than the entire facility. Even a deemed necessary provider is allowed to relocate without loss of status as long as certain criteria are met to show that the new facility is serving essentially the same community as prior to the move. While the non-provider based units might comply with the CAH relocation requirements, the provider-based unit would not. Therefore, the provider-based unit would not be allowed to relocate.

We are presently in the process of constructing a medical office building which will be attached to the Hospital. The building will replace numerous wood frame office buildings which have primarily been adapted from personal residence over the years. These structures vary from forty to one hundred years in age. Given their age and their original intended use, these buildings are no longer appropriate as medical office buildings by today's standards. The designation of a provider-based unit is site specific,

so while the original location will be grand-fathered, a new location on the campus of the Hospital would not be allowed.

Prohibit the Provision of Services to a Rural Area

In addition to limiting access to care as discussed above, attempting to coordinate rule requirements between one type of provider (provider based units) with another type of provider (CAH) is not practical because the two providers are so different. Provider-based units which employ physicians are much more mobile than a Hospital. Consider an example where two CAH's who are located 35 miles apart with a town equidistant between the two providers. Which of the two CAH's could provide a provider-based unit employing physicians to that town? Well, neither of them could provide the service as a provider-based unit. In this example, the two CAH's would have to be 70 miles apart for either to provide a provider-based unit to the town. Of course, depending upon the exact mileage, the unit might not qualify as an off-campus provider-based unit by violating the 35 mile rule.

For the reasons stated above, we believe that Medicare beneficiaries will unnecessarily suffer an access to care and new services. Consequently, we respectfully ask that these rules not be implemented.

Thank you for giving us the opportunity to comment on these proposed rules.

Should you have any questions, please feel free to call me at 207-858-2302.

Sincerely,

Dana C. Kempton
Associate Director

MAYO CLINIC

97

200 First Street SW
Rochester, Minnesota 55905
507-284-2511

September 12, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: File Code CMS-1392-P

Comments to Proposed Rule 72 FR 42628, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment System for CY 2008

Dear Mr. Weems:

We appreciate the opportunity to provide comments on the proposed changes to the Hospital Outpatient Prospective Payment System published in the August 2, 2007 Federal Register.

"Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)"

We request CMS reassign HCPCS codes for MRgFUS (0071T and 0072T) to APC 0127 for calendar year 2008, which more accurately reflects our hospital charges and costs. The MRgFUS procedure offers patients a non-surgical treatment option that allows them to return to normal activities the following day. Patients who undergo the MRgFUS procedure have fewer disability days (i.e. days of missed work or days in bed) and decreased use of medical resources.

The proposed rule would move the procedures into APC 0067 with a proposed payment of $3,918.43. It is our opinion the payment rate for this procedure has, and continues to be, far below the cost incurred by hospitals. Information from InSightec indicates the average hospital costs are between $8,200 and $9,000.

The proposed APC 0067 does not appropriately reflect the cost of the MRgFUS treatment planning and delivery required to treat patients. MRgFUS treatment planning is performed immediately prior to treatment delivery and does not have separate treatment planning coding available like other stereotactic radiosurgery services. Therefore, the cost of treatment planning must be captured as part of the APC assignment.

"OPPS Specified Covered Outpatient Drugs – Pharmacy Overhead"

CMS should not require hospitals to report pharmacy overhead services as separate charges with specific revenue codes. Hospital pricing has included these costs as part of the drug for decades. We understand CMS' desire to have drug administration services package the pharmacy overhead costs; however, this is not how hospital cost and charge structures are configured. Drug administration costs are reported in cost centers that provide patient care. Hospital pharmacy costs are in the same department as the cost of the drugs and the services are not similar to that drug administration services. We believe that packaging costs from an overhead cost center into costs of department that provides patient care is not the best way to match costs and charges. Attempting to separate the pharmacy overhead component of hospital drug pricing is contrary to how hospitals manage and report their business. Hospitals do not charge dispensing fees in the same manner retail pharmacies do. The costs are package into the service and HCPCS reporting of the drug they are related to. We request Medicare remove the intent to require hospitals to develop a charge for pharmacy overhead and report it in a separate revenue code.

"Cardiac Rehabilitation Services"

We support CMS' initiative to reimburse cardiac rehabilitation on a per hour basis. We encourage CMS to work with the AMA to expand the existing CPT definition for these codes (93797, 93798) to allow for time-based reporting. This will allow providers and suppliers to use existing codes for all payers and decrease the administrative burden associated with different codes and billing processes based on payer type. We encourage CMS to retain the existing CPT definitions of these codes, with the exception of adding the time element.

"Proposed Changes to the Ambulatory Surgical Center Payment System"

We believe the CMS concept of budget neutrality in this proposal is incorrect. CMS proposes to increase the number of procedures that may be performed in an ASC. The procedures to be added are performed by a variety of specialties. By raising the reimbursement for procedures concentrated within certain specialties (i.e., vascular, orthopedics and urology), a greater number of these services will be performed in the ASC. In computing budget neutrality, it appears that exactly the same pool of dollars should cover, in full, the payment for these expanded services. We do not believe it was the intention of Congress or CMS to secure twice as many services for the same number of dollars. Every new service that is added to the ASC list forces the facility payment for other procedures, such as GI endoscopies, to be lower if performed in the ASC.

In summary, the expansion of the ASC list will likely move many procedures to be performed in the ASC and it is unlikely that the current proposed payment methodology

will cover the cost from the same pool of funds. Certain specialties such as gastroenterology and pain management will have a greater decrease in payment under this methodology. If ASC payments are to become a percentage of the Outpatient Prospective Payment System (OPPS), CMS should adopt a bi-level approach where specialties that provide the majority of their services in the ASC are paid at a at a higher tier/level of payment and a second tier of payment for other specialties less likely to use the ASC for their procedures, set at a percentage of the facility fee.

"Reporting Quality Data for Annual Payment Rate Updates"

While we concur with CMS' initiatives to improve health care quality, we strongly urge CMS to delay implementation of the hospital outpatient quality program and give hospitals adequate time to prepare.

While the emergency department acute myocardial infarction measures are well established, the additional physician quality reporting incentive (PQRI) measures are new to hospital outpatient departments. It is unlikely most hospitals will have knowledge of the PQRI measures or the outcomes of the measures. It is difficult and resource intensive for hospitals to prepare for quality measures in a very short timeframe without more specific details including measure specifications applicable to the hospital outpatient setting. A delay in implementation until July 1, 2008 should allow most hospitals adequate time to prepare for and initiate the reporting of hospital outpatient measures.

Further, we urge CMS to postpone publishing the hospital outpatient measures until 2009. This will allow hospitals time to internally evaluate the measures before publicly reporting.

*****

Thank you for the opportunity to comment on this proposed rule and for consideration of our comments. If you have any questions, please contact Brenda Mickow (507) 284-1871 or me at (507) 284-4627.

Very truly yours,

Ronald W. Grousky
Director, Medicare Strategy

RWG:rpv

PAINCARE
CENTERS, INC

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August 28, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
PO Box 8011
Baltimore, MD 21244-1850

Re: CMS – 1392-P: Proposed changes to the hospital outpatient prospective payment system and CY 2008 payment rates: proposed changes to the ambulatory surgical center payment system and CY 2008 payment rates

To Whom It May Concern:

I am the Medical Director of PainCenters, Inc in New Hampshire. We are a multidisciplinary Pain Management practice. We have 12 providers and we treat pain with medications, injection procedures. We also offer Physical Therapy, Acupuncture, Massage Therapy, Reiki Therapy, Psychotherapy, Chinese Medicine, and Nutrition. We provide care to approximately 2600 patients a month. One of the most powerful interventions we offer is Spinal Neurostimulators. Spinal Neurostimulators have been around for over 40 years now. Their success in treating neuropathic pain, back pain, peripheral vascular disease, Reflex Sympathetic Dystrophy, Causalgia, and Migraines has been well established. This intervention has made a tremendous difference in the lives of many of our patients over the years. As the technology of Spinal Neurostimulators has improved over the years, so has its effectiveness.

We live in a world of rechargeable batteries. Our cell phones, PDA's, laptops, cordless phones, iPods, digital cameras, and automobiles all have rechargeable batteries. In the old days, the nonrechargeable batteries for Spinal Neurostimulators were huge. Implanting them in patients was challenging since because of their size, patients found them uncomfortable and the pressure caused by such large batteries put stress on wounds and resulted in incisions opening up and infections requiring removal of the batteries and hospitalization for intravenous antibiotics. Furthermore, these devices use more energy to operate and the old nonrechargeable batteries sometimes only lasted a few months to a year before being depleted.

With the advent of rechargeable batteries, we are now able to provide superior relief for our patients. The rechargeable batteries are a fraction of the size and are thus more comfortable for patients and have less risk of causing undue tension of incisions which leads to better wound healing, less infections and less hospitalizations. Furthermore, peripheral nerve stimulation requires smaller batteries that can be placed in the extremities and so need to be smaller as well.

With rechargeable batteries, we can use the energy it takes to control a patient's pain, hence the reason for placement of the Spinal Neurostimulator in the first place.

These devices are readily placed in Ambulatory Surgery Centers. The advantage is that Ambulatory Surgery Centers are cleaner environments than hospital operating rooms since hospitals are contaminated with such virulent organisms such as MRSA and VREF since people with infections stay in hospitals where they get powerful antibiotics. This leads to resistant strains of bacteria and more infections in surgical patients. Clearly it is advantageous to perform such procedures in Ambulatory Surgery Centers since these procedures can be performed on an ambulatory basis.

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Dr. O'Connell's
PAINCARE
CENTERS, INC

If you reduce the payment for the Spinal Neurostimulators as you propose, you will prevent patients from having these procedures performed in the Ambulatory Surgery Centers. An analogous situation would be if you reduced the payment for arthroscopic equipment in ambulatory surgery centers and stop the Orthopedic Surgeons from performing ambulatory knee surgeries and forcing them to operate on people's knees in hospital operating rooms by opening the entire leg up. It's just a giant step backward.

Another analogous situation would be cataract surgery. About thirty years ago, cataract surgery was performed in hospitals under general anesthesia. The patients spent a week in the hospital and ended up wearing enormously thick glasses. Nowadays, cataract surgery is performed in Ambulatory Surgical Centers under topical anesthesia and the patients walk out the door within an hour seeing just fine.

I understand that you are looking to reduce the cost of health care, but forcing everyone to use older and inferior technology while exposing the patients to more risk and getting lousy results is simply not the way. Please take a moment to reflect the quality of care you would choose for yourself or your loved ones. Being penny wise and pound foolish is simply ridiculous. The United States is a first world nation, not a third world nation.

Thank you for your attention and your consideration.

Sincerely,

Greenspan

Joshua Greenspan M.D.
Medical Director, PainCenters, Inc.

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September 12, 2007

Mr. Kerry Weems, Director
Centers for Medicare & Medicaid Services
Dep't of Health and Human Services
Attn: CMS - 1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

VIA EXPRESS MAIL

Dear Mr. Weems:

I commend CMS for seeking to improve access to care while also trying to keep down the related costs and eliminating abuse of service. *However, as a patient with 3 forms of Dystonia (Cervical, Oralmandibular & Dysphonia), the 3rd most prevalent form of movement disorder after Parkinson's & Essential Tremor, I object strenuously to the following pending proposals:*

1) Reducing the payment formula or physician-injectable drugs for 2008. I urge you to maintain the current payment formula, and

2) Do not package the payment of these services together but continue to pay for them separately.

The acceptable standard of treatment for Dystonia is injections of BOTOX, an injectable form of botulinum toxin into the specific muscle points that are in spasms causing distortions in the body and great pain if not treated. Anyone can inject BOTOX....but not just anyone can inject it successfully. It takes special training and the use of an EMG machine to identify the pencil point area's of the muscles affected by the particular form of dystonia a patient has.

To inject BOTOX without using an EMG machine to detect the pin-point area's of spasm would most likely eliminate any relief, or minimal relief, of the patient.

Most Dystonia patients travel hundred's of miles to specialists for Botox injections which, except for invasive surgery, is the standard of care for this horrible disease which has no known cause nor cure. There are far too few neurologists & other movement disorder specialists now treating Dystonia, or who have the training for treating Dystonia. Your proposed changes will only result in hospitals pressuring doctors not to use EMG machines and the injections will most likely not provide successful relief.

I know of several doctors who've stopped giving Botox injections because the payment formula now existing is insufficient to cover their costs. If CMS reduces

payment for Botox as an injectable drug even further, there will be hundreds of other doctors abandon their Dystonia patients.

Your 2 proposals will in the case of Dystonia patients leave them with no choice other than invasive, expensive surgery that will end up increasing the cost of healthcare for Dystonia patients rather than reducing costs as you allude to be doing with the pending proposals.

DO NOT MAKE THESE CHANGES!

Ken Williams

KLW/s

Senator Richard Shelby
Senator Jeff Sessions
Representative Bachus

UF | UNIVERSITY of FLORIDA

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The Congenital Heart Center

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August 17, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P. O. Box 8018
Baltimore, MD 21244-8018

Re. File Code: CMS-1385-P, CODING—ADDITIONAL CODES FROM 5-YEAR REVIEW

To CMS:

I am writing regarding the proposed change to bundle CPT 93325 into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, and 93350 when provided together.

As a pediatrician at The Congenital Heart Center at the University of Florida, this is of particular concern to me because:

1. I do not believe the appropriate process has been followed with respect to this change. After significant interaction and research between the RUC and the appropriate specialty societies (in this case The American College of Cardiology and the American Society of Echocardiography), the CPT editorial panel has recommended that a new code be established that would bundle 93325 with 93307 to be implemented on January 1, 2009. The RUC is scheduled to evaluate the recommended relevant work and practice expense for the new code at its upcoming meeting. The CPT editorial panel did not recommend that the list of the above echo codes be bundled as well with 93325.

   This new code is fully expected to address any outstanding issues relative to Medicare Utilization of 93307, and has been analyzed at length by appropriate national medical societies, the CPT editorial panel, and the RUC. However, as a result of this proposed regulatory action by CMS, we are faced with resolving, in an accelerated timeframe of less than two months, an issue that directly impacts a distinctly non-Medicare population of pediatric cardiology practices, and which is normally addressed over a multiyear period. Further, because the actions of CMS are contrary to the normal process for such changes and the resultant compressed timeframe, the specialty societies have not been able to effectively work with their membership to evaluate the proposed change in a reasoned, methodical manner that would serve the interests of all parties.

2. The surveys performed to set the work RVUs for almost all of the echo codes utilized specifically by pediatric cardiologists and affected by this proposed change were performed more than 10 years ago. As a result, particularly with respect to 93325, the RVUs are reflective of a focus on the cost of technology and not the advances in care that have been developed as a result of the technology. Particularly among pediatric cardiologists, much needed new surveys would provide evidence that the work and risk components of the procedures that involve Doppler Color Flow Mapping have evolved to the point where the relative value of the procedures have shifted to a significantly greater work component and a lesser technology component.

This shift is reflected in the development of national standards such as those present in the Intersocietal Commission for the Accreditation of echocardiography Laboratories (ICAEL) initiative to develop and implement an echo lab accreditation process. The focus of this initiative is on process, meaning work performed, and not on the technology associated with the provision of echocardiography services. This echocardiography accreditation initiative will be mandated by many payors within the next year.

In 1997 there were specific echocardiography codes implemented in CPT for congenital cardiac anomalies to complement the existing CPT codes for echocardiography for non congenital heart disease. "The codes were developed by the CPT Editorial Panel in response to the American Academy of Pediatrics and the American College of Cardiology's request to delineate more distinctively the different services involved in *assessing* and *performing* echocardiography on infants and young children with congenital cardiac anomalies." (CPT Assistant 1997)

Consistent with this, I have significant concern with the continued approach (of which this bundling proposal is an example) of placing adult and pediatric patients in the same grouping when it comes to the evaluation of the work associated with providing care to these significantly different patient populations. Because the adult population is larger than the pediatric population, the RVUs for procedures that are common to both are established exclusively using adult patients as the basis. The work and expense associated with providing care to pediatric patients is not considered. The inaccuracies that result from this approach can be linked to anatomical differences between pediatric and adult patients (size, development, etc.- see references from the CPT Assistant below) as well as the basic issue of getting a child to be still while performing complex imaging procedures.

CPT Code 93325 describes Doppler color flow velocity mapping. This service is typically performed in *conjunction* with another echocardiography imaging study to define structural and dynamic abnormalities as a clue to flow aberrations and to provide internal anatomic landmarks necessary for positioning the Doppler cursor to record cardiovascular blood flow velocities.

Pediatric echocardiography is unique in that it is frequently necessary to use Doppler flow velocity mapping (93325) for diagnostic purposes and it forms the basis for subsequent clinical management decisions. CPT Assistant in 1997 references the uniqueness of 93325 for the pediatric population stating that Doppler color flow velocity is"...even more critical in the neonatal period when rapid changes in pressure in the pulmonary circuit can cause significant blood flow changes, reversals in fetal shunts and delayed adaptation to neonatal life." It should also be

recognized that Doppler flow velocity mapping is an essential medical service being provided to patients with congenital and non-congenital heart disease in the pediatric population.

The following vignettes will illustrate the importance of the Doppler color flow velocity mapping (93325) remaining as a separate and distinct medical service and as an add-on code (+) for pediatric echocardiography services. These are just a few examples of the many complex anatomic and physiologic issues that pediatric cardiologists face on a daily basis when performing echocardiograms on infants, children, and adults with complex congenital or non-congenital heart disease. These are not unusual cases for pediatric cardiologists.

Vignette 1 (quoted from CPT Assistant 1997) (example of Congenital Heart Disease)

"A three-day-old neonate with transposition of the great vessels was initially treated with an atrial septostomy with a planned arterial switch procedure at seven days. On the third day post Raskind balloon septostomy increasing cyanosis is seen with saturation dropping to the low 70's. A repeat Transthoracic echocardiography (93304) with color flow Doppler study is performed *(color flow Doppler is coded in addition as 93325)* the physician reviews the echocardiographic images and prepares a report. The echocardiogram shows a closed patent ductus arteriosus and a small atrial septal defect. The child is returned to the cath-lab for a repeat septostomy and prostaglandin is restarted."

Vignette II (example of non-congenital heart disease)

A two-month-old infant is referred by the pediatrician to a pediatric cardiologist for a persistent murmur in an otherwise healthy infant. The pediatric cardiologist is concerned about a patent ductus arteriosus as a possible diagnosis. A ductus arteriosus, connecting the pulmonary artery and the aorta, is an essential structure during fetal life. Normally, the ductus arteriosus closes in the first few days after birth in health term infants. A persistent ductus arteriosus can give rise to long-term complications and needs to be followed carefully to evaluate if further intervention is needed (medical vs. surgical). Echocardiography permits an accurate diagnosis of patent ductus arteriosus with assessment of both the hemodynamic impact if there is a shunt. Estimated pulmonary artery pressure is obtained by Doppler imaging and can also exclude other associated defects. Color flow Doppler will be able to outline the flow of a patent ductus arteriosus from the aorta to the pulmonary artery. Color flow Doppler in this baby revealed no cardiac defects or patent ductus arteriosus and the murmur was determined to be innocent.

Vignette III (example of congenital heart disease)

An eight-year-old child (or a twenty-three-year old adult), with complex cyanotic congenital heart disease (functional single ventricle) is post-op completion of fenestrated Fontan procedure several years ago. He has had progressive decrease in saturation over the last year. There are several possible explanations and the pediatric cardiologist performs an echocardiogram to help determine the etiology. Color flow Doppler (93325) is essential to help elucidate the postoperative anatomy and blood flow patterns, but the process is complex and time-consuming involving assessment of the surgically constructed Glenn anastomosis between the superior vena cava and pulmonary artery, assessment for obstruction to flow through the bulboventricular foramen,

assessment for significant AV valve or semilunar valve insufficiency, and assessment for collateral vessels directing venous (desaturated blood) into the heart that may have developed over time. Any or all of these findings will then help dictate the next step in the care of this patient.

3. I am concerned that this change would adversely impact access to care for pediatric cardiology patients. Pediatric cardiology programs provide care not only patients with the resources to afford private insurance, but also, to a large extent, to patients covered by Medicaid or with no coverage at all. Because a key impact of this change will be to reduce reimbursement for pediatric cardiology services across all payor groups, the resources today that allow us to support programs that provide this much needed care to our patients will not be sufficient to continue to do so should the proposed change to bundle 93325 with other pediatric cardiology echocardiography codes be implemented.

   Thus the effect of this change on pediatric cardiology programs throughout the country will be an increase in the need for subsidies from already resource-challenged children's hospitals and academic programs, or a significant increase in Medicaid reimbursement for the proposed bundled services, in order for pediatric cardiology patients to have the same access to care and resources that they do today.

I strongly urge CMS to withdraw the proposed change with respect to bundling 93325 with other pediatric cardiology echocardiography codes until such time as an appropriate review of all related issues can be performed, working within the prescribed process and timeframe, in order to achieve the most appropriate solution.

Thank you for your consideration of this serious matter.

Sincerely,

Shelley W. Collins, MD
The Congenital Heart Center
University of Florida
Gainesville, FL

SWC:lre